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510(k) Summary for the
Lutronic Corporation AccuSculpt II Laser System

SEP 23 2010

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92(c).

1. **General Information**

Submitter:	Lutronic Corporation #403-2,3,4, Ilsan Technotown 1141-1 Baeksok-Dong, Ilsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	June 4, 2010

2. **Names**

Trade Name:	AccuSculpt II Laser System
Common Name:	Laser System
Classification Name:	Laser Instrument, Surgical, Powered Product Code: GEX Panel: General & Plastic Surgery

3. **Predicate Devices**

Lutronic Corporation PowerLipo (AccuSculpt) Laser System (K082096)
Sciton, Inc. Profile Multi-Platform System (K070388)

4. **Device Description**
   The AccuSculpt II Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The system console is the heart of the AccuSculpt II Laser System and contains the Nd-YAG optical system, laser system control, fiber delivery system with handpiece, system control module with an embedded processor, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the LCD display.

5. **Indications for Use**
   The AccuSculpt II Laser System is indicated for use the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The AccuSculpt II is further indicated for laser assisted lipolysis.

6. **Substantial Equivalence**
   The AccuSculpt II Laser System has the same indications for use, technological characteristics and principles of operation as the predicate devices. Therefore, the subject device is substantially equivalent to the previously cleared predicate devices.

7. **Performance Data**
   No performance data was provided since no new questions of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

SEP 23 2010

Re: K101573
Trade/Device Name: AccuSculpt II Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 23, 2010
Received: August 24, 2010

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101573

SEP 23 2010

Device Name: AccuSculpt II Laser System

Indications for Use:

The AccuSculpt II Laser System in indicated for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The AccuSculpt II is further indicated for laser assisted lipolysis.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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